CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED AMENDMENT OF INTELLECTUAL PROPERTY REGULATIONS FOR NON-PROFIT ORGANIZATIONS – SECTIONS 100304, 100306 AND 100308

HEARING DATE: None Scheduled.

SUBJECT MATTER OF PROPOSED AMENDMENTS: Intellectual Property Policy for Non-Profit Organizations

SECTIONS AFFECTED: The proposed regulations amend Chapter 3 and sections 100304, 100306 and 100308 of Title 17 of the California Code of Regulations.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

SECTION 100304. BIOMEDICAL MATERIALS.

Purpose:

This section requires grantees to share biomedical materials described in published scientific articles for research purposes within a certain time after a receipt of a request unless legally prohibited from doing so. The section provides for CIRM-approved deviation in some circumstances and provides that authors may provide requestors with information on how to reconstruct or obtain the material. The section requires materials to be shared without cost or at cost. The regulation clarifies in the first sentence that it applies to materials "first created under CIRM funding." The regulation also clarifies that materials are to be shared either at no cost or at the actual cost of providing the material without an allocation of costs for overhead, research, discovery or other non-direct costs of providing the material.

The proposed amendments adopt the same provisions as recently promulgated by the agency in Title 17, California Code of Regulations section 100404.

Subdivision (a) states that a Grantee shall share Publication-related Biomedical Material that results from CIRM-funded Research, for bona fide purposes of research in California. Such materials are to be shared without cost to the requestor or at the actual cost of providing the materials without an allocation of costs for overhead, research, discovery or other non-direct costs of providing the materials.

Subdivision (b) indicates the time to comply with a request – 60 days, and indicates there can be no bias against the affiliation of the requestor. The purpose is to ensure prompt response and provision of materials to requestors and to avoid discrimination.

Subdivision (c) allows for alternatives to the sharing requirement as indicated, with CIRM's prior approval. The purpose is to provide relief if the number of sharing requests becomes a financial burden for the Grantee; if sharing would conflict directly with the business of the Grantee; if sharing would pose a public health risk; or if the request is otherwise inappropriate as determined by CIRM.

Subdivision (d) offers an alternative to sharing the materials, to wit: the Grantee may provide requestors with the information necessary to reconstruct or obtain identical material.

Subdivision (e) provides a reasonable timeline for the duration of the sharing requirement and accounts for the business model of certain tools companies by allowing relief from sharing obligations (with CIRM prior approval) in the event the materials are made broadly commercially available.

Subdivision (f) allows a Grantee to require the requestor execute an industry-standard Material Transfer Agreement restricting the use and dissemination of such materials.

Subdivision (g) A Grantee has no obligation under these regulations to share third party materials described in publications of CIRM-funded Research such as raw materials purchased by the Grantee to develop or synthesize the Publication-related Biomedical Material or other materials covered by third party intellectual property rights, or if the Grantee is legally prohibited from doing so.

Rationale:

It is expected that intellectual property of all types will be created as a consequence of CIRM grants to both for- and non-profit institutions and the policies in these two areas should be in harmony. The amendments are intended to provide recipients of CIRM funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with CIRM funds and is designed to assist recipients in complying with their obligations under the Bayh-Dole Act and CIRM funding policy. In order to achieve maximum public benefit, data and biomedical materials (including research tools) should be as freely available as possible in the public domain.

That said, in order to ensure vital industries are not unduly burdened by sharing requirements that directly conflict with their business models, and that a balance is struck between sharing of materials and cooperation in the advancement of cures and therapies, the regulation describes circumstances under which CIRM may allow relief from the sharing obligations. By requiring CIRM prior approval, the agency is able to ensure the exceptions are utilized in good faith and allows the CIRM to monitor and control exemptions from the regulation's requirements.

SECTION 100306. LICENSING CIRM-FUNDED PATENTED INVENTIONS:

Purpose:

This section describes the responsibilities of grantees for licensing activities of CIRM-funded patented inventions.

Subdivision (d) allows exclusive licenses for inventions relevant to therapies and diagnostics only to organizations with plans to provide access at time of commercialization to resultant therapies and diagnostics for uninsured California patients. The noticed language referencing the "federal Medicaid price" for drugs is replaced with the requirement that exclusive licensees will provide drugs at prices negotiated pursuant to the California Discount Prescription Drug Program to eligible Californians under that program. The second to last sentence clarifies that if a provider of drugs would have to provide them at a lower price than that which would be required under these regulations, then the regulation would not preempt that lower price. The last sentence alerts grantees that the access plans may be made available in the public setting of an ICOC meeting for review.

The proposed amendments harmonize the existing regulation with the terms recently enacted by the ICOC in Title 17, California Code of Regulations section 100407, Access Requirements for Products Developed by For-Profit Grantees, by stating grant recipients' exclusive licensees are bound by the terms of that regulation.

Subdivision (a) of section 100407 states that a grantee (or, by terms of an Exclusive License, its exclusive licensee) must submit a plan to afford uninsured Californians access to a Drug, as defined in Title 17, California Code of Regulations, section 100401, subdivision (e), the development of which was in whole or in part the result of CIRM-funded Research. (1) A Grantee must submit this access plan to CIRM at the time the Drug is commercialized; (2) The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Grantee or its exclusive licensee; (3) CIRM will review the access plan and may make it available for review by the ICOC and the public; (4) The Grantee or its exclusive licensee is responsible only for providing the Drug itself, not any costs of administering the Drug or other attendant care.

Subdivision (b) of section 100407 states that a Grantee (or its exclusive licensee) must provide a Drug, the development of which was in whole or in part the result of CIRM-funded Research, at a price as provided in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) (or a successor statewide prescription drug discount program) to eligible Californians under this program.

Subdivision (c) of section 100407 states that a Grantee or its exclusive licensee must sell a Drug, the development of which is in whole or in part the result of CIRM-funded Research, and which is purchased in California with public funds (as defined in Title 17, California Code of Regulations, section 100401, subdivision (q)) at any benchmark price described in the California Discount Prescription Drug Program or a successor statewide prescription drug discount program.

Subdivision (d) of section 100407 states that the regulation is not intended, and the regulation shall not be construed, to preempt or prevent any other requirement under state or federal law or regulation, or agreement or contract, that would result in selling a Drug at a lower price than provided under the regulation.

Rationale:

As a consequence of expenditure of the "first dollar" of CIRM funding, the grantee's exclusive licensee agrees to provide a plan (at the time of commercialization) to provide to uninsured California residents access to resultant therapies. The access plan shall be consistent with industry standards extant at the time of commercialization. This will ensure that Californians without insurance are able nonetheless to have improved access to therapies developed with the financial assistance of California's taxpayers.

Access plans comprise one of three components of our regulations concerning access to Californians. The first is to require Grantees or their exclusive licensees to submit a plan to CIRM to afford uninsured Californians access to a Drug. The second requires Grantees or their exclusive licensees to participate in the CalRx Discount Prescription Drug Program (or a later iteration) for discounts to drugs. The third component requires Grantees or their exclusive licensee to provide drugs at the benchmark prices described in the CalRx program (or a later iteration) to entities that purchase drugs with public funds.

The language of subdivision (a) was developed with the knowledge that we cannot predict what a drug or therapy will be and therefore cannot prescribe at this point in time what the particulars of such an access plan would look like. Moreover, the economics of treatments and therapies for orphan diseases are typically vastly different from more major or common chronic diseases, and this also has a significant effect on the model and particulars of a given type of access plan, making it all the more difficult to prescribe. The goal is to ensure, nevertheless, that whatever is proposed is typical for that drug or therapy.

In addition, the licensees will provide the therapies at a discount price to residents whose therapies are purchased in California by public funds. For drugs generated as a consequence of CIRM funding, grantees agree to provide drugs at benchmarks described in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) to eligible Californians under that program.

SECTION 100308. REVENUE SHARING

Purpose:

This section describes the requirements of grantees with respect to the sharing of revenues obtained by licensing and developing CIRM-funded inventions.

Subdivision (c): Where multiple sources of funding were used for the creation of the patented invention, the return to the State of California of any revenues shall be proportionate to the support provided by the CIRM relative to the other funding.

The proposed amendment states that the amount of CIRM funding of the patented invention shall be divided by the total of funding provided by all sources, and that fraction shall be multiplied by 25. That numeral is the percentage due to the State of California of Net Licensing Revenue.

Rationale:

The proposed amendment clarifies how the proportional return to the state shall be calculated.

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